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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,341	06/21/2005	Scott Eugene Conner	X-15463	1424
25885	7590	08/14/2007		
ELI LILLY & COMPANY PATENT DIVISION P.O. BOX 6288 INDIANAPOLIS, IN 46206-6288			EXAMINER CHU, YONG LIANG	
			ART UNIT 1626	PAPER NUMBER
			NOTIFICATION DATE 08/14/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No. 10/540,341	Applicant(s) CONNER ET AL.	
	Examiner Yong Chu	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 6, 8-39, 41-54, 56-59 and 63-65 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 16-20, 22, 25, 27, 28, 32, 34-39, 41, 43-45, 47-49 and 52-54 is/are rejected.
- 7) ☒ Claim(s) 1-3, 16-20, 22, 25, 27-28, 32, 34-39, 41, 43-45, 47-49, and 52-54 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>06/21/2005</u> | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 5,6,8-15,21,23,24,26,29-31,33,42,46,50,51,56-59 and 63-65.

DETAILED ACTION

Claims 1-3, 5-6, 8-39, 41-54, 56-59, and 63-65 are currently pending in the instant application.

Information Disclosure Statement

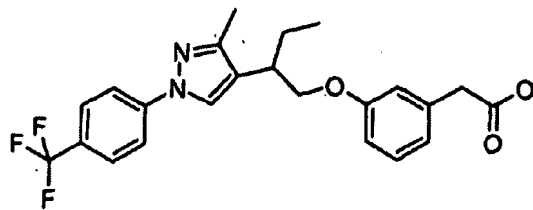
Applicant's Information Disclosure Statement, filed on 06/21/2005 has been considered. Please refer to Applicant's copies of the PTO-1449 submitted herewith.

Priority

This application is a 371 of PCT/US03/39119 filed on 12/31/2003, and claims the benefit of U.S. Provisional Patent Application 60/438,563, filed on 01/06/2003.

Response to Lack of Unity

The response to the restriction request with provisionally election of Group III (claims 1-3, 5-6, 8-39, and 41-54 (in part)), and elected species of the compound of



Example 136

with traverse by Applicants'

representative, MaCharri Vorndran-Jones dated on 05/29/2007, has been considered.

To traverse the restriction requirement, Applicant needs to specifically point out the error in the previous Office action, MPEP § 818.03(a). Otherwise, the traversal is an incomplete response, and the restriction requirement is maintained. In addition, the elected species does not read in Group III. A telephonic interview was conducted on

07/30/2007 to resolve the discrepancy. An agreement has been reached regarding the new elected scope of invention, which is described in the present Office action.

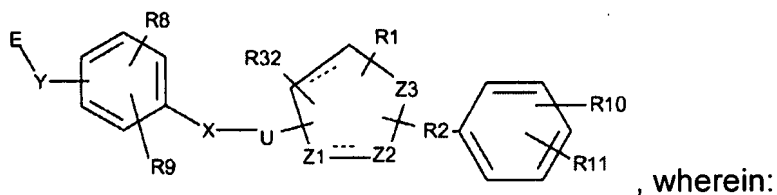
Status of the Claims

Claims 5-6, 10-15, 33, 39, 46, and 50-51 are further withdrawn from further consideration by Applicant as being drawn to non-elected inventions due to restriction requirement. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and/or element and would require separate search considerations. In addition, a reference that anticipates one invention would not render obvious the other invention.

Elected and Examined Subject Matter

The scope of the invention of the elected subject matter and the examined subject matter is as follows:

A compound, or a salt or solvate thereof of Formula (I''')



R2 is a single bond, and bond to **Z3**;

X is a single bond;

Y is a single bond;

E is $-\text{CH}_2\text{COOH}$;

R1 is H; **R8** is H, or alkyl; **R9** is H or alkyl;

R10 is CF_3 ; and **R11** is H;

R32 is H, C₁-C₆alkyl, or C₁-C₆alkyloxy;

U is an aliphatic linker replaced with an O;

Z1 is C, **Z2** is N, and **Z3** is N;

and the remaining substituents are as defined in claim 1.

As a result of the election and the corresponding scope of the invention identified supra, claims 8-9, 21, 23, 24, 26, 29-31, 42, 56-59, 63-65, and the remaining subject matter of claims 1-3, 16-20, 22, 25, 27-28, 32, 34-39, 41, 43-45, 47-49, and 52-54 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The withdrawn compounds and process of use contain method claims and compounds with varying functional groups, which are chemically recognized to differ in structure, function, and reactivity.

Therefore, claims 1-3, 16-20, 22, 25, 27-28, 32, 34-39, 41, 43-45, 47-49, and 52-54 will be examined on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

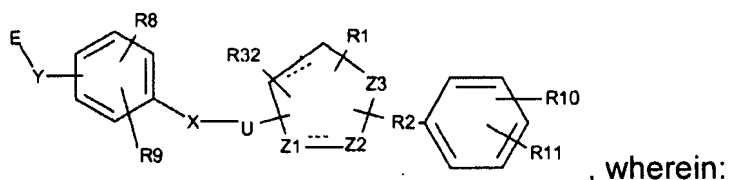
A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 16-20, 22, 25, 27-28, 32, 34-39, 41, 43-45, 47-49, and 52-54 are rejected under 35 U.S.C. 102 (a) and (e) as being anticipated by Kimura et al., (WO 2003-JP6389, (the '389 application), filed on 05/22/2003, and published on 12/04/2003).

Applicants' claims relate to the compounds of formula (I''')



R2 is a single bond, and bond to **Z3**;

X is a single bond;

Y is a single bond;

E is $-\text{CH}_2\text{COOH}$;

R1 is H; **R8** is H, or alkyl; **R9** is H or alkyl;

R10 is CF_3 ; and **R11** is H;

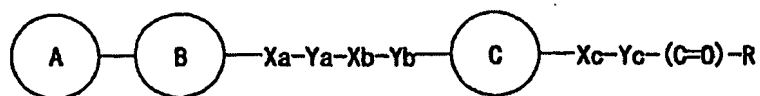
R32 is H, $\text{C}_1\text{-C}_6$ alkyl, or $\text{C}_1\text{-C}_6$ alkyloxy;

U is an aliphatic linker replaced with an O;

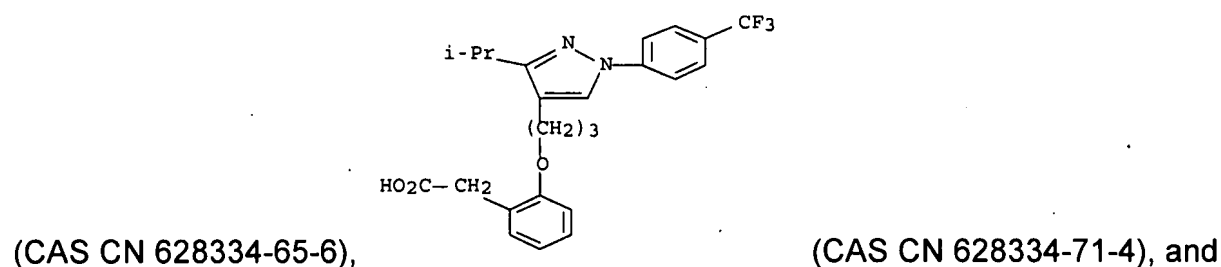
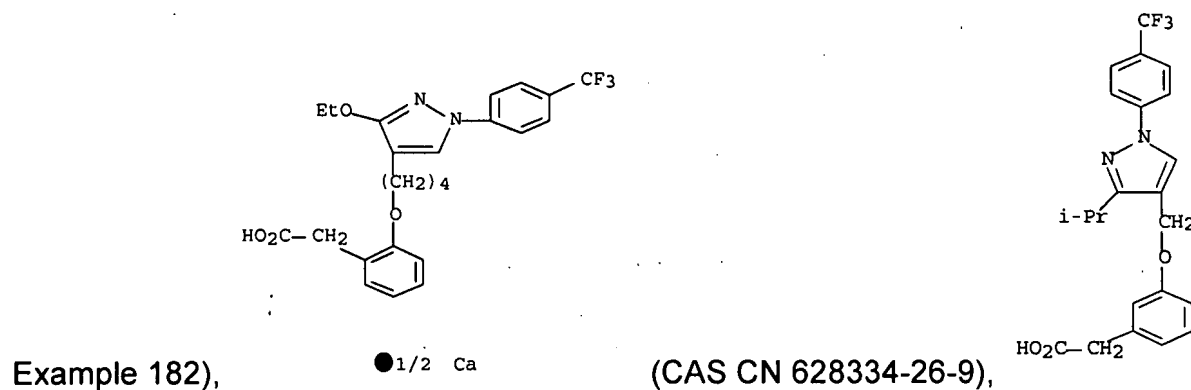
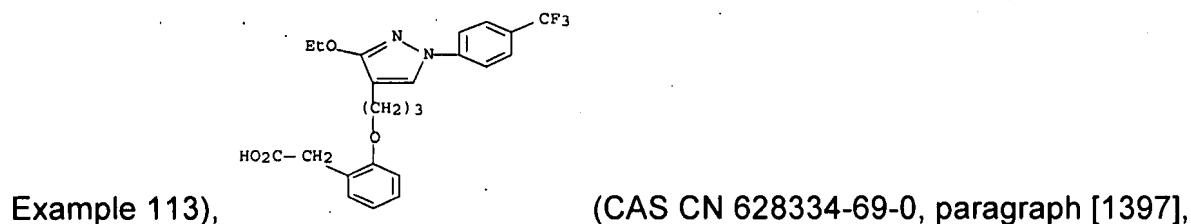
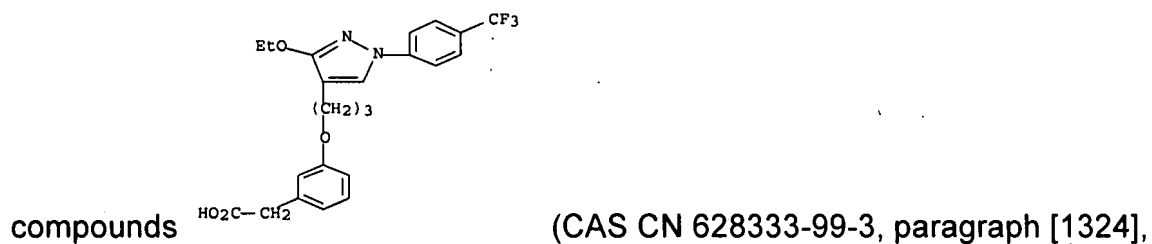
Z1 is C, **Z2** is N, and **Z3** is N;

and the remaining substituents are as defined in claim 1.

Maekawa et al. disclose a compound with a generic formula (I)



of claim 1, and several specific



the other compounds cited in PTO-892 Form. These compounds are claimed useful as an agent for treating diabetes.

Because the compound claims are rejected, the composition claims comprising the said compound are rejected either.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

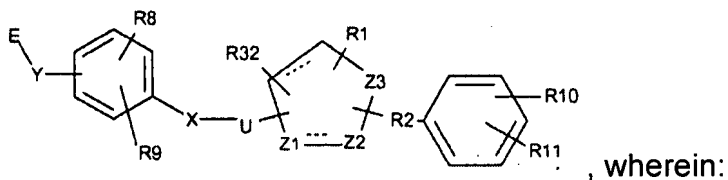
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 16-20, 22, 25, 27-28, 32, 34-39, 41, 43-45, 47-49, and 52-54 are rejected under 35 U.S.C. 103 (a) as unpatentable over the '389 application.

Applicants' claims relate to the compounds of formula (I''')



R2 is a single bond, and bond to **Z3**;

X is a single bond;

Y is a single bond;

E is $-\text{CH}_2\text{COOH}$;

R1 is H; **R8** is H, or alkyl; **R9** is H or alkyl;

R10 is CF₃; and **R11** is H;

R32 is H, C₁-C₆alkyl, or C1-C6alkyloxo;

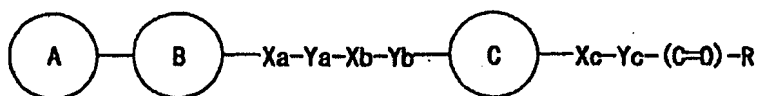
U is an aliphatic linker replaced with an O;

Z1 is C, **Z2** is N, and **Z3** is N;

and the remaining substituents are as defined in claim 1. These compounds are claimed useful as an agent for treating diabetes mellitus.

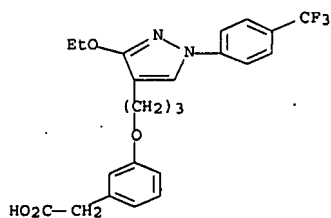
Determination of the scope and content of the prior art (MPEP §2141.01)

The '389 application disclose a compound with a generic formula (I)



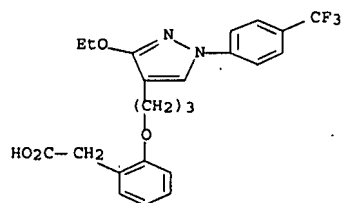
of claim 1, and several specific

compounds

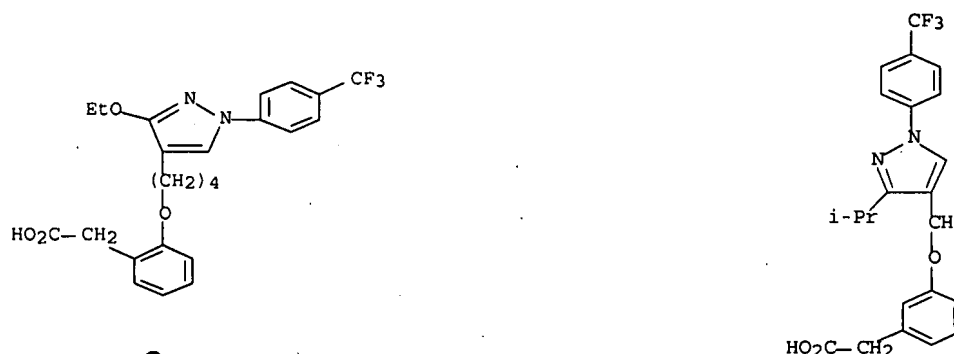


(CAS CN 628333-99-3, paragraph [1324],

Example 113),



(CAS CN 628334-69-0, paragraph [1397],

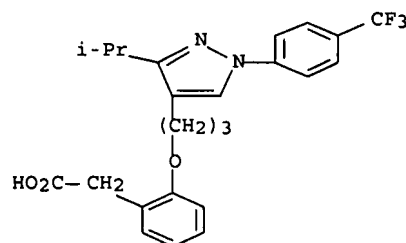


Example 182),

● 1/2 Ca

(CAS CN 628334-26-9),

(CAS CN 628334-65-6),



(CAS CN 628334-71-4), and

the other compounds cited in PTO-892 Form. These compounds are claimed useful as an agent for treating diabetes.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the '389 application prior art and the instantly claimed compounds, is that the prior art teaches the compounds wherein the linker **U** is -CH₂-O-, -(CH₂)₃-O-, and -(CH₂)₄-O- with one end-aliphatic carbon replaced with, but does not teach the compounds as instantly claimed, wherein **U** is the other aliphatic-O- linker, such as -(CH₂)₂-O-, or -(CH₂)₂-O-(CH₂)-

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The instantly claimed compounds would have been obvious over the prior art compounds, because one skilled in the art would have been motivated to prepare homolog of the compounds with **U** as variable length of linker with -O replaced at

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different linker position. To those skilled in the chemical art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. The desire to modification of the prior art is motivated by searching useful agents for treating diabetes.

Because the compound claims are unpatentable, the composition claims comprising the said compound are unpatentable either.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 52 and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. "S conformation" or "R conformation" is used to define chirality of one unsymmetrical carbon of a compound. However, the specification fails to describe which chiral carbon of the compound in claim 2 having R or S conformation.

Claim Objections

Claims 1-3, 16-20, 22, 25, 27-28, 32, 34-39, 41, 43-45, 47-49, and 52-54 are objected to for containing elected and non-elected subject matter. The elected subject matter has been identified supra. Applicant should amend the claims according to the scope of the invention.

Conclusion

- Claims 1-3, 16-20, 22, 25, 27-28, 32, 34-39, 41, 43-45, 47-49, and 52-54 are rejected.
- Claims 1-3, 16-20, 22, 25, 27-28, 32, 34-39, 41, 43-45, 47-49, and 52-54 are objected.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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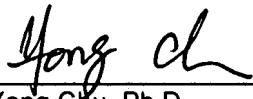
published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.


For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).



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